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23869 7590 07/09/2908 HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE			EXAMINER	
			JUEDES, AMY E	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Application No. Applicant(s) 10/533,981 GEIJTENBEEK ET AL. Office Action Summary Examiner Art Unit AMY E. JUEDES 1644 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 27 February 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 53-67 is/are pending in the application. 4a) Of the above claim(s) 58-62.65 and 67 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 53-57,63,64 and 66 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 05 May 2005 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. Notice of Draftsperson's Patent Drawing Review (PTO-948)

Paper No(s)/Mail Date _

3) Information Disclosure Statement(s) (PTO/SB/08)

Notice of Informat Patent Application
Other: notice to comply.

Application/Control Number: 10/533,981 Page 2

Art Unit: 1644

DETAILED ACTION

1. Applicant's election of group I, drawn to a method of stimulating an immune response, claims 53-57 and 63-67, in the reply filed on 2/27/08 is acknowledged. Furthermore, applicant has elected a glycoconjugate comprising a fucose residue as the species of glycoconjugate, and a method for treating cancer as the species of method. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 58-62 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 65 and 67 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

Claims 53-57, 63-64, and 66 read on the elected invention and are being acted upon.

- 2. The drawings are objected to because the Y-axis label for Figure 4 is missing. Additionally, the specification indicates that Figure 1A is a table of structures, however, the Table is not present in the drawings filed 5/5/05. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.
- 3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR \S 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR \S 1.821 through 1.825 for the reason(s) set forth below:

The specification discloses nucleotide and amino acids sequences on page 78 and in Figures 19 and 44, however, no CRF, sequence listing, or statement that the two are identical has been filed. Correction is required.

4. Claims 55 and 63 are objected to because of the following informalities: Claim 55 recites Lewis bloodgroup antigen ${\rm Le^x}$,

Art Unit: 1644

Le', Le', "Le' of LDNF". It is assumed that this is a typographical error, and the claim is intended to recite "Le' or LDNF", as recited in original claim 8 or on page 4 of the specification. Claim 63 recites a derivative "an/or" multimer thereof. It is assumed that this is a typographical error, and that the claim is intended to recite a derivative "and/or" multimer. Appropriate correction is required.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53-57, 63-64, and 66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, there is insufficient written description to demonstrate that applicant was in possession of the claimed genus of glycoconjugates comprising a fucose residue or at least one end-standing N-acetylglucosamine or a "derivative" thereof, or a glycoconjugate comprising a "part, derivative and/or analogue" of a Lewis bloodgroup antique.

The instant claims are drawn to a method of inducing an immune response by providing a C-type lectin receptor with a glycoconjugate comprising a fucose or N-acetylglucosamine residue, or a "derivative" thereof. The specification discloses on pages 3-6 that said "derivatives" have C-type lectin binding activity. The claims further encompass providing qlycoconjugates comprising a Lewis bloodgroup antigen or a C-type lectin binding "part, derivative and/or analogue" thereof. This might include "derivatives", "parts", or "analogues" with different stereochemistry, different functional groups, or different carbohydrate residues". Thus, the claims encompass a broad range of structurally different carbohydrate analogs or derivatives that function to bind to a C-type lectin receptor. However, the specification does not disclose a single species of derivative or analogue, nor does the specification provide any teaching regarding how the structure of the derivatives/analogues of the claims correlates with the claimed function of binding to C-type lectin receptors. Furthermore, while carbohydrate derivatives are known in the art, they are an extremely diverse and complex set of molecules (see Wang et al., page 705 and Marcaurelle et

Art Unit: 1644

- al.). Additionally, there is no art recognized correlation between the structure of fucose, N-acetylglucosamine, or Lewis blood group antigen derivatives, and the claimed function of binding to C-type lectins. Thus, one of skill in the art would conclude that the specification fails to provide adequate written description to demonstrate that Applicant was in possession of the claimed genus. See Eli Lilly, 119 F. 3d 1559, 43, USPQ2d 1398.
- 6. Claims 53-54, 56-57, 63-64, and 66 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

- A) A method comprising providing an antigen presenting cell with a glycoconjugate that has been provided with a fucose residue or N-acetylglucosamine or derivative "and/or" multimer thereof (Claim 53, 56, and 63, and dependant claims 54, 57, 64, and 66).
- B) A method comprising providing an antigen comprising a glycoconjugate, wherein the antigen is an "antigen of a pathogen" (Claim 57).
- C) A method wherein the antigen "lacked a fucose residue or an end standing N-acetylglucosamine" prior to providing said antigen therewith (Claim 56).
- D) A method of augmenting or inducing an effective immune response comprising providing an antigen presenting cell with a ligand comprising an antigen and a glycoconjugate (Claim 63).

In the Preliminary Amendment, filed 9/19/05, Applicant indicates that support for the new claims can be found in the original claims, as well as in the specification on pages 18-21.

A review of the specification fails to reveal support for the new limitations.

Art Unit: 1644

Regarding A), original claim 35 was drawn to using a glycoconjugate comprising an antigen and a fucose residue, or a derivative or multimer thereof, for stimulating an antigen specific immune response in an individual. The specification on page 19 discloses a method of stimulating an immune response in an individual employing an antigen comprising a glycoconjugate comprising a fucose residue, an N-acetylglucosamine, or a derivative or multimer thereof. However, the specification does not disclose a glycoconjugate comprising a fucose residue or an N-acetylglucosamine or derivative "and" multimer thereof, as recited in the instant claims.

Regarding B), at page 18, the specification discloses a method of stimulating an immune response in an individual by providing an antigen through a C-type lectin receptor on an antigen presenting cell. The specification further discloses that the antigen may comprise a tumor antigen. However, the specification does not disclose stimulating an immune response with an antigen from a pathogen, as claimed.

Regarding C), the specification on page 19 discloses providing a tumor antigen with a carbohydrate of the invention (i.e. a fucose or N-acetylglucosamine), wherein the tumor antigen lacks said carbohydrate. However, the specific disclosure of a tumor antigen lacking a fucose/N-acetylglucosamine does not provide adequate support for the more broad claim of the instant application, which encompasses any antigen lacking said fucose/N-acetylglucosamine.

Regarding D), the specification discloses on page 18-19 a method of stimulating an immune response in an individual by providing antigen through a C-type lectin receptor on an antigen presenting cell using an antigen comprising a glycoconjugate. Thus, the specification discloses an in vivo method of inducing an immune response in an individual. However, claim 63 has a much broader scope than what is disclosed by the specification. The claim is drawn to a method of augmenting or inducing an immune response comprising providing an antigen presenting cell with a ligand comprising an antigen and a glycoconjugate. While the claim might encompass in vivo methods as disclosed by the specification, the claim also encompasses in vitro methods (for example, the antigen presenting cells might be "provided" with the antigen to induce an in vitro immune response). The specification only discloses stimulating an immune response in an individual.

Page 6

Application/Control Number: 10/533,981 Art Unit: 1644

 Claims 53-57, 63-64, and 66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method for stimulating/augmenting/inducing an immune response by providing an antigen presenting cell with an antigen comprising a glycoconjugate comprising a fucose residue, an end standing N-acetylglucosamine, or a multimer thereof, or a glycoconjugate comprising a Lewis blood group antigen Le^* , Le^\vee , Le° , or LDNF,

does not reasonably provide enablement for:

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention, in re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

"The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." In re Fisher, 427 F.2d 833, 839, 166 USPO 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling (MPEP 2164.03)" The MPEP further states that physiological activity can be considered inherently unpredictable.

Art Unit: 1644

The specification provides insufficient data to enable claims drawn to the method as broadly claimed. The instant claims are drawn to a method for stimulating or augmenting an immune response comprising providing an antigen presenting cell with a antigen comprising a glycoconjugate comprising a fucose reside or an end standing N-acetylglucosamine or a derivative thereof. In another embodiment, the glycoconjugate comprises a Lewis bloodgroup antigen Lex, Ley, Le, Cor LDNF, or a C-type lectin binding part, derivative, or analogue thereof. Antigen presenting dendritic cells express C-type lectin receptors such as DC-SIGN. Thus, administering an antigen comprising a glycoconjugate that binds to a C-type lectin receptor such as DC-SIGN might be suitable for inducing an immune response to the antigen by targeting the antigen to antigen presenting dendritic cells. DC-SIGN is known to have affinity for carbohydrates such as N-acetylglucosamine, fucose, and Lewis blood group antigens (see Hovius et al., page 2). However, the instant claims encompass inducing an immune response by providing a glycoconjugate comprising derivatives of fucose or Nacetylglucosamine, or any C-type lectin binding part, derivative, or analogue of a Lewis blood group antigen.

Regarding the predictability of the art, it is noted that carbohydrates are the most complex and structurally dense of all naturally occurring materials (see Wang et al., page 705). Additionally, the high degree of functionalization and diverse stereochemistry of carbohydrates make the application of combinatorial chemistry to synthesize carbohydrate derivatives extremely laborious and challenging (See Marcaurelle et al.). Thus based on the highly unpredictable nature of the art as well as the breadth of the claims, the instant specification must provide a sufficient disclosure to enable one of skill in the art to make and use the glycoconjugate derivatives, parts, or analogues, as broadly claimed.

The specification discloses on pages 5-6 that the fucose/N-acetylglucosamine derivatives comprise the same C-type lectin binding activity and may be generated through modification of the fucose or N-acetylglucosamine residue. No specific examples of derivatives are provided, nor does the specification providing any teaching or guidance as to what modifications or changes to the fucose or N-acetylglucosamine residues can be tolerated, while still maintaining the ability to bind to C-type lectins and induce an immune response. Regarding the C-type

Art Unit: 1644

lectin receptor binding part, derivatives, or analogues of Lewis blood group antigens, the specification discloses that modifications such as sialyation abrogates binding to DC-SIGN. However, the specification does not disclose any parts, derivatives, or analogues of Lewis blood group antigens that maintain C-type lectin binding ability, nor does the specification provide any teaching or guidance as to which modification of the Lewis blood group antigens can be tolerated in order to maintain their C-type lectin binding function. Accordingly, the method as broadly claimed must be considered highly unpredictable. Given said unpredictability, the method of the instant claims must be considered to require undue experimentation.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claim 53-57, 63-64, and 66 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 7,285,642.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

 ${\tt Application/Control\ Number:\ 10/533,981}$

Art Unit: 1644

The '642 patent teaches a method of increasing an immune response in an animal comprising presenting an antigen to dendritic cells in a form that can bind to a C-type lectin receptor (see column 1 in particular). The '642 patent teaches that the C-type lectin receptor can be DC-SIGN (see column 12 in particular). The '642 patent teaches that the method of increasing the immune response can be performed by administering an antigen conjugated to a compound that can bind to the C-type lectin (see columns 9-11 in particular). The '642 patent teaches that the compound for binding to the C-type lectin can be a fucose carbohydrate, including L-fucose (see column 6 and 9-10, in particular). The '642 63251 teaches that the antigen can be a cancer antigen, including pg100, MAGE, BAGE, MART-1, or an fragment or epitope thereof (i.e. an antigen lacking a fucose residue), and that the method can be performed to generate an immune response against tumor cells (i.e. to treat cancer, see column 10, in particular). Furthermore, since Lewis bloodgroup antigens such as Lex, Ley, etc. comprise a fucose residue, the fucose carbohydrate taught by the '642 patent can be considered a C-type lectin binding "part, derivative, or analogue" of a Lewis bloodgroup antigen.

Thus, the reference clearly anticipates the invention.

10. Claim 53-57, 63-64, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/63251.

WO 00/63251 teaches a method of increasing an immune response in an animal comprising presenting an antigen to dendritic cells in a form that can bind to a C-type lectin receptor (see page 1 in particular). WO 00/63251 teaches that the C-type lectin receptor can be DC-SIGN (see page 20 in particular). WO 00/63251 teaches that the method of increasing the immune response can be performed by administering an antigen conjugated to a compound that can bind to the C-type lectin (see pages 15-16 in particular). WO 00/63251 teaches that the compound for binding to the C-type lectin can be a fucose carbohydrate, including L-fucose (see page 15 in particular). WO 00/63251 teaches that the antigen can be a cancer antigen, including pg100, MAGE, BAGE, MART-1, or an fragment or epitope thereof (i.e. an antigen lacking a fucose residue), and that the method can be performed to generate an immune response against tumor cells (i.e. to treat cancer, see page 16 in particular). Furthermore, since Lewis bloodgroup antigens such as Lex, Ley,

Art Unit: 1644

etc. comprise a fucose residue, the fucose carbohydrate taught by WO 00/63251 can be considered a C-type lectin binding "part, derivative, or analogue" of a Lewis bloodgroup antigen.

Thus, the reference clearly anticipates the invention.

11. Claims 53-57, 63-64, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Sabbatini et al., 2000.

Sabbatini et al. teach a method of stimulating an immune response in a patient to treat cancer comprising administering an antigen (KLH) that has been conjugated to Le' pentasaccharide (see page 79 and 81 in particular). Sabbatini et al. also teach that the antigen conjugate is a tumor antigen (see page 79 in particular). Additionally, KLH is an antigen lacking a fucose residue. Furthermore, the administration of the antigen Le' conjugate would inherently result in the antigen being provided to DC-SIGN on antigen presenting cells in the patient.

Thus, the reference clearly anticipates the invention.

12. Claims 53-57, 63-64, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/43677.

WO 98/43677 discloses a conjugate comprising a carbohydrate and a peptide antigen that can be administered to induce antitumor immunity and treat cancer (see page 15 in particular). WO 98/43677 discloses that the carbohydrate may be the Le antigen (which comprises a fucose residue), and that the peptide antigen can be a tumor peptide or tumor antigen (i.e. an antigen lacking a fucose residue, see pages 12-13 in particular). Furthermore, the administration of the peptide antigen Le conjugate would inherently result in the antigen peptide being provided to DCSIGN on antigen presenting cells in the patient.

Thus, the reference clearly anticipates the invention.

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the

Art Unit: 1644

examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 53-57, 63-64, and 66 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-7, 9, and 15 of U.S. Patent No. 7,285,642. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '642 patent are drawn to a method of increasing an immune response in an animal comprising administering a compound conjugated to an antigen, wherein the compound binds to SEO ID NO: 2 (i.e. DC-SIGN). The `642 patent further claims that the antigen can be a cancer antigen, and the compound can be a fucose carbohydrate, including L-fucose. Thus, the '642 patent claims a method of increasing an immune response employing an antigen that has been conjugated to a fucose carbohydrate (i.e. and antigen "provided with" a fucose residue). The '642 patent further claims that the method can be used to generate an anti-tumor immune response (i.e. as a treatment for cancer). Furthermore, since Lewis bloodgroup antigens such as Lex, Ley etc. comprise a fucose residue, the fucose carbohydrate claimed in the '642 patent can be considered a C-type lectin binding "part, derivative, or analogue" of a Lewis bloodgroup antigen.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 6am - 2pm, Monday through Friday.

Art Unit: 1644

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy E. Juedes Patent Examiner Technology Center 1600

/G.R. Ewoldt/ Primary Examiner, Art Unit 1644